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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/535,345	02/15/2006	Graeme Semple	22578-005US1 079.US2.PCT	6159
26204 7590 03/18/2009 FISH & RICHARDSON P.C. P.O. BOX 1022 MINNEAPOLIS, MN 55440-1022			EXAMINER CHUNG, SUSANNAH LEE	
			ART UNIT 1626	PAPER NUMBER
			NOTIFICATION DATE 03/18/2009	DELIVERY MODE ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

PATDOCTC@fr.com

<b>Office Action Summary</b>	<b>Application No.</b> 10/535,345	<b>Applicant(s)</b> SEMPLE ET AL.	
	<b>Examiner</b> SUSANNAH CHUNG	<b>Art Unit</b> 1626	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 17 December 2008.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 4,7,10,11,14,17-22,26-28,31,41 and 43-64 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 4,7,10,11,14,17-22,26-28,31,41 and 43-64 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                       | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>12/17/08</u> .  | 6) <input type="checkbox"/> Other: _____                          |

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### **DETAILED ACTION**

Claims 4, 7, 10, 11, 14, 17-22, 26-28, 31, 41, and 43-64 are pending in the instant application. Claims 1-3, 5-6, 8-9, 12-13, 15-16, 21-25, 29-30, 32-40, and 42 are canceled.

#### ***Information Disclosure Statement***

The information disclosure statement (IDS), filed on 12/17/2008 has been considered. Please refer to Applicant's copy of the 1449 submitted herewith.

#### ***Response to Non-Final Office Action***

Acknowledgment is made of applicant's response and amendment of the claims filed on 12/17/2008.

Claims 28-31 were rejected under 35 U.S.C. 112, first paragraph, because the specification does not enable one skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims, wherein the instantly claimed compounds are directed to methods of treating a metabolic-related disorder and raising HDL comprising administering to an individual in need of such treatment a therapeutically effective amount of a compound of claim 4.

Claims 29 and 30 are canceled and new method claims 43-64 are added. Generic claim 28 has been amended to read a method of "lowering free fatty acids" in an individual using a therapeutically effective amount of a compound of claim 4. The amendments to the claims and arguments have been considered, but are not found persuasive. Applicants argue that the pending method claims are enabled because (1) nicotinic acid (niacin) was known at the time of filing to have activity in lowering

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triglycerides and free fatty acids and (2) the murine variant of the known RUP25 receptor was shown to mediate the metabolic effects of nicotinic acid, (3) nicotinic acid was known to bind and agonize the RUP25 receptor and (4) the particular species of Formula (I) also bind and agonize the RUP25 receptor. Applicants arguments are acknowledged. The studies and nonpatent literature submitted by Applicants are also acknowledged. The issue is whether the instantly claimed compounds can lower free fatty acids with a reasonable amount of certainty. Unfortunately, the art is too unpredictable to make an assertion.

Applicants refer to niacin to support the use of the instantly claimed compounds in lowering free fatty acids. Niacin is pyridine-3-carboxylic acid. The instant claims are drawn to (1H-tetrazol-5-yl)-cyclopentapyrazole compounds. Pyridine-3-carboxylic acid and (1H-tetrazol-5-yl)-cyclopentapyrazole are vastly different compounds and therefore the utility of one compound cannot be linked to the utility of the other compound. Even if the two compounds were linked, the instant disclosure lacks data as to how the binding data of the instantly claimed compounds compare to the binding data of niacin. The specification on page 57 states that certain compounds of the invention have an EC50 in the nicotinic acid binding competition assay, but which compounds and how many? In order for the instantly claimed compounds to meet the enablement requirement, the data needs to be predictable and consistent.

Therefore, claims 28, 31 and 43-64 are rejected as nonenabled for lowering free fatty acids.

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Claims 4, 7, 10, 11, 14, 17-22, 26-28, 31 and 41 were rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for compounds and compositions of claim 4, does not reasonably provide enablement for solvates or hydrates of those compounds. Applicants arguments have been considered, but are not found persuasive. Applicants argue that solvates and hydrates simply means to add water. Examiner respectfully disagrees that a solvate or hydrate is a compound with water. As stated previously, the term solvates and hydrates when read in the broadest reasonable sense can encompass a class of compounds that have different activity from regular compounds. Applicants arguments regarding other patents with the term solvates and hydrates is acknowledged, but not found persuasive because the facts of those cases are different from the instant one. Therefore, the claims are still rejected for the terms solvates and hydrates.

Claim 41 was rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Applicants amendment to the claims are acknowledged, but not found persuasive. The amendment to the claim would be convincing if it were directed to a pharmaceutical composition, but this claim is directed to a method of producing. There are no steps to this method and therefore, the claim is still indefinite.

Claims 28-31 and 41 were provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 28-31

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and 41-43 of copending application number 11/601,252. The express abandonment of the copending application obviates this rejection and it is withdrawn.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

#### ***Telephone Inquiry***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susannah Chung whose telephone number is (571) 272-6098. The examiner can normally be reached on M-F, 8am-5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph McKane can be reached on (571) 272-0699. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Golam M. M. Shameem/  
Primary Examiner, Art Unit 1626

Susannah Chung